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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/467,903	12/21/99	HOSOKAWA S	00177/522457

HM12/0329

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EXAMINER	
SCHWADRON, R	
ART UNIT	**PAPER NUMBER**
1644	4

DATE MAILED: 03/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/467,903	Hosakawa et al.
Examiner	**Group Art Unit**
Ron Schwadron, Ph.D.	1644

Responsive to communication(s) filed on _____.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

X Claim(s) 30-49 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

X Claim(s) 30-49 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

X Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

X All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

X received in Application No. (Series Code/Serial Number) 08/360,125.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

X Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Claims 30-49 are under consideration. Claims 1-29 have been cancelled.

2. The drawings have been approved by the draftsperson.

3. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821-1.825, however, this application fails to comply with the requirements for patent applications containing nucleotide sequence and/or amino acid sequence disclosures. The following procedure is to be used for cases that contain the same sequence disclosure as the parent. The applicant need not submit a new computer readable form of the Sequence Listing for this divisional application. However, (1) the specification must contain a paper copy of the Sequence Listing, (2) applicant must request in writing that the CRF in the parent case be used to prepare a file for the offspring and (3) applicant must submit a statement that the paper copy of the Sequence Listing in the offspring is identical to the computer readable form submitted in the parent case.
It is valid to use this approach to bring sequences into rule 60 continuation, divisional or CIPs as long as there are no new sequences. Applicants also need to list the appropriate sequence ID no. after any sequence that appears in the specification.
Applicant is required to fulfill these requirements. Applicant is requested to return a copy of the attached Notice To Comply with the response.

Regarding applicants comments in page 3 of the preliminary amendment filed with the instant application, (1) the specification must contain a paper copy of the Sequence Listing, (2)

applicant must request in writing that the CRF in the parent case be used to prepare a file for the offspring and (3) applicant must submit a statement that the paper copy of the Sequence Listing in the offspring is identical to the computer readable form submitted in the parent case.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 30-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,3-15 of U.S. Patent No. 5,264,221. Although the conflicting claims are not identical, they are not patentably distinct because of the following reasons. While the claimed inventions differ in scope, the liposome containing an antibody recited in the instant invention is a member of the genus recited in claims 1,3-15 of U.S. Patent No. 5,264,221 and thus makes obvious the inventions of claims 1,3-15 of U.S. Patent No. 5,264,221. Both sets of claims encompass similar liposome/antibody conjugates. Therefore, the two sets of claims under consideration in this rejection would have been prima facie obvious in view of each other to one of ordinary skill in the art at the time the invention was made for the aforementioned reasons.

7. Claims 30-49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 37,41-44,46-49,51 of

copending Application No. 08450363. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. While the claimed inventions differ in scope, both sets of claims encompass the liposome/antibody fragments as per recited in claim 30, etc. Therefore, the two sets of claims under consideration in this rejection would have been prima facie obvious in view of each other to one of ordinary skill in the art at the time the invention was made for the aforementioned reasons.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 30-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "antibody fragment" in claims 30,35,40 or 45. The scope of the term "antibody" encompasses compositions containing antibody fragments not disclosed in the specification (eg. such as Fv or Fd or $F(ab)_2$). There is no written description in the specification as originally filed of the claimed conjugate or composition containing said conjugate wherein the conjugate contains a " antibody fragment " per se. The scope of the term "antibody fragment" as recited in the claim encompasses conjugates or compositions containing said conjugates wherein antibody fragments not disclosed in the specification (eg. such as Fv or Fd or $F(ab)_2$) are used. There is also no support in the specification as originally filed for the recitation of "$F(ab')_2$" in claims 34,39,44 or 49. The specification, pages 11 and 12, discloses the use of Fab' derived from $F(ab')_2$ for the preparation of the claimed invention, but there is no disclosure of the use of $F(ab')_2$ in the claimed invention. The specification merely discloses the use of $F(ab')_2$ to prepare Fab', wherein the Fab' are then

used in the claimed invention. Similarly, there is no disclosure in the specification as originally filed of conjugates containing "fragments thereof" or conjugates containing antibody fragments that are encompassed by said term (eg. Fd or Fv). There is no written description in the specification as originally filed of the claimed invention (eg. the claimed invention constitutes new matter).

Regarding applicants comments in the instant amendment, the specification, pages 11 and 12, the "first method(1)" refers in the specification to a method for use in thiolation of an antibody (eg. see page 12, line 3). It does not disclose that said method is practiced with a $F(ab')_2$ or antibody fragment. In addition, the Traut et al. reference to which applicant refers to discloses thiolation of intact protein. Furthermore, none of the references which applicant refers to are cited in the specification. Regarding the Hosokawa et al. declaration filed with the instant application, said declaration is not relevant to the issue under consideration. There is still no disclosure in the specification as originally filed of the scope of the claimed invention using antibody fragments per se or $F(ab')_2$. While such fragments and conjugates were known in the prior art, there is no disclosure in the specification as originally filed that such fragments were used in the claimed invention. There is no support in the specification as originally filed for the recitation of "antibody fragment " in claims 30,35,40 or 45. The scope of the term "antibody fragment" encompasses compositions containing antibody fragments not disclosed in the specification (eg. such as Fv or Fd or $F(ab)_2$). There is no written description in the specification as originally filed of the claimed conjugate or composition containing said conjugate wherein the conjugate contains an "antibody fragment" per se. The scope of the term "antibody fragment" encompasses conjugates or compositions containing said conjugates wherein antibody fragments not disclosed in the specification (eg. such as Fv or Fd or $F(ab)_2$) are used. The specification, pages 11 and 12, discloses the use of Fab' derived from $F(ab')_2$ for the preparation of the claimed invention, but there is no disclosure of the use of $F(ab')_2$ in the claimed invention. The specification merely discloses the use of $F(ab')_2$ to prepare Fab', wherein the Fab' are then used in the claimed invention. Similarly, there is no disclosure in the specification as originally filed of conjugates containing "antibody fragments" or conjugates containing antibody fragments that are encompassed by said term (eg. Fd or Fv). There is no written description in the specification as originally filed of the claimed invention (eg. the claimed invention constitutes new matter). Regarding the specification, page 11, last paragraph, said passage of the specification refers to

methods of conjugating an antibody to a liposome, not methods of conjugating an antibody fragment. The claimed invention is not disclosed on pages 1,3,12,36,37 or 41 of the specification. There is no written description in the specification as originally filed of the claimed invention (eg. the claimed invention constitutes new matter). In addition, the CAFC opined in Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977) that written description of an invention extends only to that which is disclosed in prior application, and does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. The CAFC stated in Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977) that:

3. Patentability/Validity -- Specification -- Written description (§ 115.1103)
Patent's entitlement to earlier filing date extends only to that which is disclosed in prior application, and does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed; one shows that one is "in possession" of invention of patent by describing invention, with all its claimed limitations, not that which makes it obvious, and although prior application need not describe claimed subject matter in exactly same terms used in claims, prior specification must contain equivalent description of claimed subject matter, and description which renders obvious invention for which earlier filing date is sought is not sufficient.

The CAFC also stated in Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977) that:

The invention is, for purposes of the 'written description' inquiry, whatever is now claimed .") (emphasis in original). One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. Although the exact terms need not be used in haec verba , see Eiselstein v. Frank , 52 F.3d 1035, 1038, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995) (" [T]he prior application need not describe the claimed subject matter in exactly the same terms as used in the claims.. . . "), the specification must contain an equivalent description of the claimed subject matter. A description which renders obvious the invention for which an earlier filing date is sought is not sufficient.

10. No claim is allowed.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-2454. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644